Application No. 10/112,184
Art Unit: 3763

In the Specification:

On page 4, please amend the first paragraph of the Brief Description of the Drawings as follows:

A1

The novel features of the invention are ~~se~~ set forth with particularity in the appended claims. The invention itself, however, both as to organization and methods of operation, together with further objects and advantages thereof, may best be understood by reference to the following description, taken in conjunction with the accompanying drawings in which:

On page 7, please amend the second paragraph as follows:

A2

During assembly of one potential embodiment the elongated needle 30, the left body member 40 and right body member 50 of the elongated needle 30 are pushed together. Once the left body member 40 and the right body member 50 are pressed together, a thin-walled sleeve of high strength tubing is slipped over the elongated needle and is shrink fitted into place. The shrink tubing holds the left body member 40 and the right body member 50 together for easier handling prior to adhesive curing. In addition, the shrink tubing makes the exterior of the elongated needle 30 smoother for reduced insertion forces. ~~(show shrink tubing in Fig. 2)~~

On page 7, please amend the third paragraph as follows:

A3

Referring back to Figure 3, there is shown the right body member 50 of the elongated needle 30, separated from the left body member 40, which has been omitted from this figure for clarity. The right body member 50 has upper and lower ends comprising alternating male and female portions or members, 42 and 52, which alternate and are arranged axially along the length of the right body member 50 of the elongated needle 30. In addition to the male and female members, 42 and 52, there is an upper female distal member 54 and a lower male distal member 45, both of which are located at ~~he~~ the distal end of the right body member 50. The upper female distal member 54 is located just below the distal end of the cutter lumen 32 and above the distal end of the vacuum chamber lumen 34. At the proximal end of the right body member 50 are three female receivers 56 which surround the vacuum manifold 26 at the proximal end of the right body member 50.

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Please amend the paragraph starting at line 33 on page 7, as follows:

Still referring to figure 3, needle ~~20~~ 30 includes a cutter tube liner 22, which helps keep adhesive out of the lumen to provide a smooth surface thereon. Liner 22 generally abuts in the inner surface of cutter 20 along lumen 32. The distal end 31 of liner 22 is proximal to port 36 but otherwise is disposed along the length of lumen 32. The cutter tube liner 22 is formed from a thin-walled extrusion of a low-friction, abrasion-resistant plastic, such as polypropylene, polyetherimide or polyethersulfone. The cutter tube liner 22 provides a smooth, low-friction, abrasion-resistant surface for the cutter 21. The cutter tube liner 22 also acts as an aid for sealing vacuum and fluid leakage in that it isolates the cutter lumen 32 from the vacuum chamber lumen 34 and ensures that fluid and material from the cutter lumen 32 does not get sucked into the vacuum chamber 34 by vacuum suction in the vacuum chamber lumen 34. Isolating the cutter lumen 32 from the vacuum chamber lumen 34 may be preferable because the cutter lumen 32 and vacuum line 27, and the vacuum chamber lumen 34 operates on the second vacuum line 28.

Please amend the paragraph starting on line 14 of page 8 as follows:

Still referring to Figure 3, another feature that is included in the preferred design of the invention to enhance performance is the outside diameter of the left body member 40 and right body member 50 could be stepped very slightly, if needed, to compensate for the thickness of the cutter tube ~~inner~~ liner 22. This is, the cutter lumen 32 would be very slightly larger than the inside diameter of the cutter tube liner 22, which is a thin walled structure.

Please amend the paragraph starting at line 21 of Page 8 as follows (to delete improper spacing):

Referring again to Figure 4 there is shown an exploded isometric view of the elongate needle 30 of the and held vacuum assisted biopsy device 10 of figure 1. Both the left body member 40 and the right body member 50 of the elongated needle 30 are shown. The female features 52, which are arranged axially on the right body member 50. Also, the male features 42, which are arranged axially on the left body member 40, mate to the female features 52, which are arrange axially on the right body member 50. Also, the male features 42 are arranged

axially on the right body member 50 mate to the female features 52 which are arranged axially on the left body member 40.

Please amend the paragraph beginning on line 31 of page 8 as follows:

In addition to male and female members, 42 and 52, which are arranged axially and mate, the left body ~~half~~ member 40 and right body member 50 have additional features that mate at both the proximal and the distal ends. At the proximal end of the right body member 50 are three female receivers 56 which surround the vacuum manifold 26. At the proximal end of the left body member 40 are three male bosses 46 which surround the vacuum manifold 36 and correspond to the three female receivers 56 on the right body member 50. When the left body member 40 and the right body member 50 are pushed together, the three female receivers 56 on the proximal end of the left body member 40. The proximal end of the elongated needle 30 is thus, retained by the three female receivers 56 and three male bosses 46, which mate at the proximal end of the elongated needle 30.

Please amend the paragraph starting on line 4 of page 10 as follows:

Still referring to figure 4, during assembly of the elongated needle 30, sufficient adhesive is applied to the left body member 40 ~~and right body member 40~~ and right body member 50, to fill the narrow axial spaces between the male and female members, 42 and 52, which mate. After this, the left body member 40 and right body member 50 are pressed together. The adhesive that is used should be cured using light, heat, or other appropriate means for the particular types of adhesive that is being used. For a light cured adhesive, light could be directed inside of the cutter lumen 32 and the vaccum lumen 34 using light stick optics if necessary.

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Please amend the first paragraph on Page 11 as follows:

Figure 5 shows and exploded isometric view of the needle tip 60 of the elongated needle 30 of the hand held vacuum assisted biopsy device 10 of figure 1 as viewed from the proximal side thereof. The needle tip 60 has two halves; a composite tip member 70, and a composite hub member 80. Both the composite tip member 70 and the composite hub member 80 are preferably molded from a magnetic Resonance Imaging (MRI) compatible resin such as Ultem or Vectra ceramic or other MRI compatible materials known to those skilled in the art ~~is sharp~~. The composite tip member 70 has a three-sided pyramidal shaped point, but may also have other shapes. The composite tip member 70 has a hollow cavity 74 and protruding connectors 76. The two protruding connectors 76 are inserted into the two receiving holes 82 on the composite hub member 80 when the composite hub member 80 is pushed into the composite tip member 70 during assembly. Cavity preferably contains a capsule 90 made from a material which will leave ~~and~~ MRI artifact. Having a capsule 90 made from ~~and~~ MRI artifact leaving material is necessary because since the elongated needle 30 is made of an MRI compatible resin, the elongated needle 30 does not show up on an MRI scan. Therefore, it is difficult for a physician to discern the orientation of the elongated needle 30 during ~~and~~ MRI scan. MRI artifact leaving material 90 solves the aforementioned problems in that a needle tip 60 leaves a small, but not troublesome artifact on an MRI scan. This small, artifact indicates the orientation of the elongated needle 30 relative to the sight of biopsy, and where the tissue receiving bowl begins during ~~and~~ MRI scan. The MRI artifact leaving material 90 that is preferred is a capsule of Gadolinium. However, there are other materials that could be put into the hollow cavity 74 of the composite tip member 70 that would leave and acceptable MRI artifact. These include, but not limited to: liquid Gadolinium, Titanium Wire, Aluminum, Copper, Brass Iron, and Bronze.

Please amend the paragraph starting on line 28 of page 11 as follows:

Figure 6 shows an exploded isometric view of the needle tip 60 of the ~~elongated needle~~ 30 of the hand held vacuum assisted biopsy device 10 of figure 1 as viewed from the distal end thereof. This figure clearly illustrated the components on the composite hub member 80. On the distal end of the composite hub member 80 is a male part 84, which pushes the MRI artifact leaving material ~~80~~ 90 down into the hollow cavity 74 on the composite tip member 70. Also located on the distal end of the composite hub member 80 is a knock out boss 86, which pushes a collected breast tissue sample into the end of the cutter ~~tube~~ 21 of the hand held vacuum assisted biopsy device 10 during a breast biopsy. The two receiving holes 82 on the composite hub member 80 receive the two protruding connectors 76 on the composite tip member 70 when the composite tip member 70 and composite hub member 80 are pushed together. The reception of the two protruding connectors 76 on the composite tip member 70 by the two receiving holes 82 on the composite hub member 80 locks the composite tip member 70 and the composite hub member 80 together, and seals the MRI artifact leaving material 90 in the hollow cavity 74 in between the composite tip member 70 and composite hub member 80.

Please amend the paragraph starting on line 19 of page 12 as follows:

After the location of the suspicious breast tissue is determined, the patient is moved outside the magnet. Local anesthesia is administered to the patient and the needle assembly ~~probe~~ 20 is inserted into the area of suspicious breast tissue.

Please amend the paragraph starting on line 23 of page 12 as follows:

After the probe is inserted into the suspicious area of breast tissue, the patient is moved back into the MRI magnet and a set of images of the breast are taken. The sets of images confirm that the needle assembly ~~probe~~ 20 is adjacent to the suspicious breast tissue, the patient is moved outside of the MRI magnet and the hand held vacuum assisted biopsy device 10 of figure 1 is then inserted into the sleeve, replacing the obturator.

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Please amend the paragraph starting on line 4 of page 13 as follows:

Once the elongated needle 30 is positioned in the area adjacent to the suspicious breast tissue, vacuum suction is applied to ~~he~~ the vacuum chamber lumen 34. The vacuum suction is applied by pressing the vacuum button 18 on the holster 15 of the hand held vacuum assisted biopsy device 10 of figure 1. Pressing the vacuum button 18 on the holster 15 opens the second vacuum line 28, which transports vacuum suction through the handpiece 12 of the hand held vacuum assisted biopsy device 10 and into the vacuum chamber lumen 34 on the elongated needle 30. The second vacuum line 28 runs through the handpiece 12 of the hand held vacuum assisted biopsy device 10 and into the elongated needle 30 through the vacuum manifold 24 at the ~~he~~ proximal end of the elongated needle 30. The vacuum suction that is applied to the vacuum chamber lumen travels from the proximal, of the distal end of the vacuum chamber lumen 34, below the interlumen vacuum holes 23. The interlumen vacuum holes 23 receive suction from the vacuum chamber lumen 34.